

Application Number 10/029,355  
Amendment dated February 3, 2005  
Responsive to Office Action mailed November 3, 2004

### REMARKS

This amendment is responsive to the Office Action dated November 3, 2004. Applicant has amended claims 1, 6, 12, 13, 18, 23, 28 and 30, and cancelled claims 2, 7, 19, 24, 51 and 52. Applicant has added new claims 53 and 54. Claims 1, 3-6, 8-18, 20-23, 25-50, 53 and 54 are pending.

### Specification

In the Office Action, the Examiner identified a minor editorial problem in the paragraph beginning at page 16, line 26 of Applicant's specification. Applicant has amended the paragraph to correct the minor editorial problem identified by the Examiner.

### Claim Objections

In the Office Action, the Examiner objected to claim 12 as including an informality. In particular, the Examiner indicated, "Applicant should replace "a report" with "the report" in claim 12, because proper antecedent basis was provided for "the report" in claim 1. Applicant respectfully disagrees with the Examiner's objection, and suggests that, in the context of further defining the recitation of "generating a report" in independent method claim 1, it is proper to re-recite the phrase "generating a method" in a dependent method claim. In other words, use of the word "a" in this situation does not lead to any confusion as to which limitation of the method is being referred to. Nonetheless, Applicant has amended claim 12 as suggested by the Examiner, for purposes of clarity, and requests that the objection to claim 12 be withdrawn.

### Status of U.S. Patent No. 6,485,979 to Kippenhan et al. (Kippenhan)

In the Office Action, the Examiner rejected claims 1, 3-4, 6-7, 9-10 and 51 under 35 U.S.C. § 102(b) as anticipated by Kippenhan et al. (US 6,485,979) (hereafter referred to as Kippenhan), and rejected claims 2, 5, 8, 11-50 and 52 under 35 U.S.C. § 103(a) as being unpatentable over Kippenhan in view of a variety of other references.

The Kippenhan patent issued on November 26, 2002, after the October 26, 2001 filing date of the present application. Consequently, the Kippenhan patent can only be prior art to Applicant's claims under 35 U.S.C. § 102(e). Additionally, the Kippenhan patent and

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Applicant's claimed invention were, at the time of Applicant's invention, respectively owned by and subject to assignment to 3M Innovative Properties Co.<sup>1</sup> Therefore, the Kippenhan patent cannot preclude patentability of Applicant's claimed invention under 35 U.S.C. § 103.<sup>2</sup>

Accordingly, Applicant respectfully traverses the rejections of claims 2, 5, 8, 11-50 and 52 under 35 U.S.C. § 103(a) as being unpatentable over Kippenhan in view of a variety of other references as improper in light of 35 U.S.C. § 103(c). However, a PCT application claiming priority from the U.S. application that issued as the Kippenhan patent published on February 15, 2001, prior to the filing date of the present application, as WO 01/10476 (PCT application). Applicant cited the PCT application to the U.S.P.T.O. in an information disclosure statement on filed January 21, 2002, which the Examiner has considered. Consequently, in this Response, Applicant responds substantively to the rejections under § 103 that rely on the Kippenhan patent, assuming that the Examiner will respond to Applicant's traversal of those rejections based on § 103(c) by citing the Kippenhan PCT application in place of the Kippenhan patent.

Applicant does not concede that the PCT application is prior art to Applicant's invention under § 102(a), or under § 102 at all, and reserves the right to establish an earlier invention date through submission of an affidavit or declaration of prior invention under 37 C.F.R. § 1.131.

#### **Claim Rejections Under 35 U.S.C. §§ 102 and 103**

In the Office Action, the Examiner rejected claims 1, 3-4, 6-7, 9-10 and 51 under 35 U.S.C. 102(b) as being anticipated by Kippenhan. The Examiner also rejected: claims 2, 8 and 11-12 under 35 U.S.C. 103(a) as being unpatentable over Kippenhan in view of U.S. Patent No. 6,148,297 to Swor et al. (Swor); claims 5, 18, 20-24, 26-27 and 52 under 35 U.S.C. 103(a) as being unpatentable over Kippenhan in view of U.S. Patent No. 6,578,002 to Derzay et al. (Derzay); claims 13-15 and 35-39 under 35 U.S.C. 103(a) as being unpatentable over Kippenhan in view of U.S. Patent No. 5,193,065 to Guerindon et al. (Guerindon); claim 16 under 35 U.S.C. 103(a) as being unpatentable over Kippenhan in view of U.S. Patent No. 6,628,777 to McIlwaine et al. (McIlwaine); claim 17 under 35 U.S.C. 103(a) as being unpatentable over

<sup>1</sup> An Assignment of the present Application to 3M Innovative Properties Co. was recorded at Reel/Frame 012420/0787 on October 26, 2001.

<sup>2</sup> See 35 U.S.C. § 103(c).

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Kippenhan in view of U.S. Patent Application Publication No. 2002/0194014 by Starnes et al. (Starnes); claims 19, 25, and 28-29 under 35 U.S.C. 103(a) as being unpatentable over Kippenhan and Derzay as applied to claim 18, and further in view of Swor; claims 30-32 and 40-44 under 35 U.S.C. 103(a) as being unpatentable over Kippenhan and Derzay as applied to claim 18, and further in view of Guerindon; claim 33 under 35 U.S.C. 103(a) as being unpatentable over Kippenhan and Derzay as applied to claim 18, and further in view of McIlwaine; claim 34 under 35 U.S.C. 103(a) as being unpatentable over Kippenhan and Derzay as applied to claim 18, and further in view of Starnes; claims 45-47 under 35 U.S.C. 103(a) as being unpatentable over Kippenhan, Guerindon, and Swor as applied to claim 35, and further in view of U.S. Patent Application Publication No. 2004/0098159 by Brown (Brown); and claims 48-50 under 35 U.S.C. 103(a) as being unpatentable over Kippenhan, Derzay, and Guerindon as applied to claim 30, and further in view of Swor and Brown.

Applicant respectfully traverses these rejections to the extent that such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

*Claims 1, 3-6, 8-18, 20-23 and 25-34*

As amended, independent claim 1 recites a method that includes arranging sterilization process information received from a sterilization facility to illustrate compliance with a sterilization process standard, and generating a report that includes the arranged information. Further, as amended, independent claim 18 recites a system which includes a network server that arranges sterilization process information received from a client computer to illustrate compliance with a sterilization process standard, and generates a report that includes the arranged information. Contrary to the Examiner's assertions, Kippenhan fails to disclose or suggest these requirements of Applicant's independent claims 1 and 18.

For example, the Examiner cited column 21, lines 52-67, and column 22, lines 36-53 of Kippenhan as disclosing arrangement of sterilization process information to illustrate compliance with a sterilization process standard. However, the cited portions of Kippenhan merely describe the provision of prompts and other information to a user to assist the user in

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complying with regulations or procedures. The cited portions of Kippenhan do not even suggest arranging sterilization process information received from a sterilization facility to illustrate compliance with a sterilization process standard, as required by claims 1 and 18 as amended.

Further, the Examiner cited column 20, lines 17-40 of Kippenhan as disclosing generation of a report based on received sterilization process information. However, the cited portion of Kippenhan merely indicates that information entered into the described article tracking system may be read by a user, and does not even appear to be suggestive of report generation. In any event, Kippenhan nowhere discloses or suggests generating a report that includes sterilization process information that has been received from a sterilization process facility and arranged to illustrate compliance with a sterilization process standard, as required by claims 1 and 18 as amended.

The other references cited by the Examiner provide no teaching that would overcome the above-identified deficiencies in the Kippenhan disclosure. For example, although Swor mentions a regulatory agency, it merely indicates that the regulatory agency receives and statistically analyzes data regarding occupational health incidents to, for example, formulate procedures, reengineer devices, or track disease (*see* Swor, column 1, lines 13-44, and column 6, lines 54-64). Swor does not even suggest that the mentioned regulatory agency evaluates compliance with a process standard, much less arrangement of data to illustrate compliance with a process standard.

Independent claims 1 and 18, as amended, also require providing a reviewer access to the report, wherein the reviewer analyzes the report to evaluate compliance with the sterilization process standard. In the Office Action, the Examiner acknowledged that Kippenhan fails to teach this requirement of claims 1 and 18, but argued that Swor teaches this requirement. However, as discussed above, Swor does not even suggest evaluation of compliance with a process standard. Consequently, Swor provides no teaching that would have motivated one of ordinary skill in the art at the time of Applicant's invention to modify the system described by Kippenhan to arrange sterilization process information received from a sterilization facility to illustrate compliance with a sterilization process standard, generate a report including the arranged information, and provide a reviewer that analyzes the report to evaluate compliance with the standard with access to the report, as required by independent claims 1 and 18.

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Dependent claims 13 and 30, as amended, further require determining consumption of a quantity of sterilization material by a sterilization facility based on the sterilization process information received from the sterilization facility. The Examiner acknowledged that Kippenhan fails to teach this requirement of claims 13 and 30, but stated that Guerindon discloses this requirement. The Examiner argued that it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify Kippenhan to include determination of consumption of sterilization material by a sterilization facility based on the Guerindon disclosure for reasons related to cost and efficiency.

However, even if one of ordinary skill were motivated to combine Kippenhan and Guerindon as the Examiner suggests, such a combination would still fail to meet the requirements of claims 13 and 30. In particular, Guerindon describes a system in which a local cell means 205 produces a missing resource signal (MSR) in response to itself determining that a predetermined amount of a resource has been depleted (*see* Guerindon, column 3, lines 29-55). The MSR causes the system described by Guerindon to direct transfer of a new quantity of the material to the cell means (*see id.*). Consequently, if one were to modify the system described by Kippenhan based on the teachings of Guerindon, the result would be a sterilization facility that itself determines whether a sterilization material has been depleted, and sends a request for replenishment of the material based on the determination. The combination would not result in a system in which a server or other entity receives sterilization process information from a sterilization facility via a computer network, and determines consumption of a quantity of a sterilization material based on the sterilization process information received from the sterilization facility.

Dependent claims 16 and 33 require providing interactive communication between technical personnel knowledgeable in sterilization processes and sterilization facility personnel. The Examiner acknowledged the Kippenhan fails to teach this requirement of claims 16 and 33, but stated that McIlwaine teaches this requirement. The Examiner argued that it would have been obvious to one of ordinary skill in the art to at the time of Applicant's invention to modify the system described by Kippenhan with the system and method of McIlwaine to provide technical support for the network-based sterilization process information management system described by Kippenhan.

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The Examiner appears to have misunderstood the requirements of claims 16 and 33. In particular, the requirements of claims 16 and 33 are not related to the provision of technical support for an information management system, as suggested by the Examiner. Instead, claims 16 and 33 require providing interactive communication between technical personnel knowledgeable in sterilization processes and sterilization facility personnel. As described in Applicant's specification, the invention may facilitate real-time delivery of expert advice regarding operation, maintenance and control of sterilization equipment and processes, the characteristics and capabilities of commercially available sterilization materials such as particular sterilants, pack lists, and indicators from technical personnel knowledgeable in sterilization processes to sterilization facility personnel (*see, e.g., Specification, page 2, lines 25-29*). Nothing in the Kippenhan or McIlwaine disclosures would even suggest providing interactive communication between such personnel to one of ordinary skill in the art at the time of Applicant's invention.

Dependent claims 17 and 34 require accumulating information concerning best practices and trends in sterilization processing from multiple network clients. The Examiner acknowledged that Kippenhan fails to disclose this requirement of claims 17 and 34, but stated that Starnes discloses this requirement. However, it appears that the Examiner has misinterpreted the scope of the Starnes disclosure.

In particular, contrary to the Examiner's suggestion, Starnes does not disclose or suggest accumulating information concerning best practices and trends from multiple network clients. Instead, Starnes merely indicates that such information is stored in a database, and made available to the network clients. Starnes is silent as to the origin of such information, and in no way suggests that it is received from user computers 14 or other network clients.

The applied references fail to disclose or suggest a number of requirements of Applicant's claims 1, 3-6, 8-18, 20-23 and 25-34, including a number of requirements of independent claims 1 and 18, as amended. For at least these reasons, the Examiner has failed to establish a *prima facie* case of unpatentability of any of claims 1, 3-6, 8-18, 20-23 and 25-34 under 35 U.S.C. §§ 102 and 103. Withdrawal of these rejections is requested.

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#### *Claims 35-44*

Like claims 13 and 30, discussed above, independent claims 35 and 40 require determining consumption of a quantity of sterilization material by a sterilization facility based on the sterilization process information received from the sterilization facility. For the reasons discussed above with respect to claims 13 and 30, the applied references fail to disclose or suggest this requirement of independent claims 35 and 44.

Additionally, dependent claims 39 and 44 further require that the received sterilization process information includes characteristics of a sterilization process, and identification of a type of the sterilization material based on the characteristics of the sterilization process. The Examiner stated that Kippenhan teaches this requirement. However, the portion of Kippenhan cited by the Examiner merely indicates that a computer may store information regarding more than one type of sterilization process and more than one type of sterilization material. Nowhere within the Kippenhan disclosure does there appear to be a suggestion of identifying a type of sterilization material based on sterilization process information received from a sterilization facility for any reason, much less for determining consumption of the material, as required by claims 39 and 44.

The applied references fail to disclose or suggest a number of requirements of Applicant's claims 35-44, including a number of requirements of independent claims 35 and 40. For at least this reasons, the Examiner has failed to establish a prima facie case of unpatentability of any of claims 35-44 under 35 U.S.C. § 103. Withdrawal of these rejections is requested.

#### *Claims 45-50*

Independent claims 45 and 48 require determining consumption of a quantity of sterilization material by a sterilization facility based on the sterilization process information received from the sterilization facility and generating a report that indicates compliance with sterilization process standards based on the sterilization process information. For the reasons discussed above with respect to independent claims 1 and 18, and dependent claims 13 and 30, the applied references fail to disclose or suggest these requirements of Applicant's independent claims 45 and 48.

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Independent claims 45 and 48 also require scheduling maintenance for sterilization equipment associated with the sterilization facility based on the sterilization process information. The Examiner acknowledged that none of Kippenhan, Guerindon, Derzey or Swor teaches this requirement, but stated that Brown does teach this requirement. The Examiner argued that it would have been obvious to modify the system described by Kippenhan to schedule maintenance for sterilization equipment associated with the sterilization facility based on the sterilization process information to allow a reviewer monitor scheduled maintenance to review compliance with sterilization process standards.

The Examiner's reasoning is flawed for two reasons. First, Brown teaches scheduling maintenance based on a process time line used to simulate and model a pharmaceutical manufacturing process (*see e.g.*, Brown, abstract). Brown does not even suggest receiving actual process information from a facility via a computer network, much less scheduling maintenance of equipment at the facility based on the actual process information. Consequently, even if the system of Kippenhan were modified according to the teachings of Brown as suggested by the Examiner, it would not meet the requirements of independent claims 45 and 48.

Second, the Examiner has provided no evidence that the cited motivation to modify Kippenhan with the teachings of Brown, to facilitate processing standard compliance monitoring, was within the prior art at the time of Applicant's invention. None of the cited reference provides any teaching suggesting that scheduling of maintenance based on process information would facilitate processing standard compliance monitoring. Nothing in the Brown disclosure suggests application of its teachings to sterilization processing facilities, or maintenance of sterilization process equipment. The Examiner has cited no other teaching within the prior art that would have motivated one of ordinary skill in the sterilization processing art to turn to a disclosure regarding pharmaceutical batch process manufacturing simulation for any modification of the system described by Kippenhan.

For at least these reasons, the Examiner has failed to establish a prima facie case for unpatentability of Applicant's claims 45-50 under 35 U.S.C. 103. Withdrawal of these rejections is requested.



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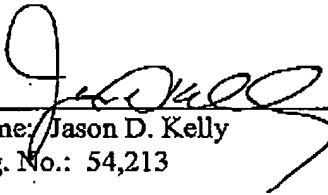
*New Claims 53 and 54*

Applicant has added claims 53 and 54 to the pending application, which recite substantially the same limitations as found within claims 16 and 33. Consequently, for the reasons discussed above with reference to claims 16 and 33, the applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. No new matter has been added by the new claims.

**CONCLUSION**

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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